PTO/SB/35 /11/68/

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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE. Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number Docket Number (Optional) PRE-APPEAL BRIFF REQUEST FOR REVIEW 1001.2240101 I hereby certify that this paper(s) is being electronically transmitted to Application Number Filed the United States Patent and Trademark Office at "Mail Stop AF. Commissioner for Patents, P.O. Box 1450, Alexandra, VA 22313-1450" 10/680 288 **OCTOBER 8, 2003** (37 CFR 1.8/a)1 APRIL 20, 2009 First Named Inventor CD. TOBY FREYMAN Signature Art Unit Examiner Typed or printed 3734 THU H. LE-TO. VIX NGUYEN name \_ Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request, This request is being filed with a notice of appeal. The review is requested for the reason(s) stated on the attached sheet(s). Note: No more than five (5) pages may be provided. I am the applicant/inventor assignee of record of the entire interest. J. SCOT WICKHEM See 37 CFR 3.71 Statement under 37 CFR 3.73(b) is enclosed. (Form PTQ/SB/98) Typed or printed name attorney or agent of record. 612,677,9050 41376 Registration number \_\_\_ Telephone number attorney or agent acting under 37 CFR 1 34. 4-20-2009 Registration number if sixting under 37 CFR 1.34 \_

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NOTE. Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required Submit multiple forms if more than one signature is required, see below?

\*Total of \_\_\_\_\_

\_\_\_ forms are submitted

## PATENT

## UNITED STATES PATENT AND TRADEMARK OFFICE

 Applicant:
 TOBY FREYMAN et al.
 Confirmation No.: 4217

 Scrial No.:
 10/680,288
 Examiner: Vi X. Nguyen

 Filing Date:
 OCTOBER 8, 2003
 Group Art Unit: 3734

 Docket No.:
 1001,2240101
 Customer No.: 28075

Title: MEDICAL DEVICE GUIDANCE FROM AN ANATOMICAL REFERENCE

## PRE-APPEAL CONFERENCE BRIEF

Mail Stop AF Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

## CERTIFICATE FOR ELECTRONIC TRANSMISSION

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APRIL 20, 2009 Date

Thu II. Le-To

Dear Sir:

Appellants have carefully reviewed the Final Office Action of November 20, 2008 and the Advisory Action of February 13, 2009. Currently, claims 1-5, 22-31, 33 and 34 are pending and have been twice rejected. Appellants hereby request a pre-appeal conference and file this pre-appeal conference brief concurrently with a Notice of Appeal. Favorable

consideration of the claims is respectfully requested.

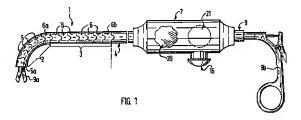
Claims 1-2, 5, 24-31 and 33-34 were rejected under 35 U.S.C. §103(a) as being unpatentable over Heckele (USPN 5,448,989) in view of Kittrell (USPN 5,693,043).

Applicants respectfully appeal the rejection because the cited prior art references do not teach or suggest each and every element of the claimed invention, singly or when viewed together. As such, these claims are allowable over these references.

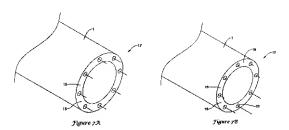
Claims 1-2, 5, 24-31 and 33-34 were rejected under 35 U.S.C. §103(a) as being unpatentable over Heckele (USPN 5.448.989) in view of Kittrell (USPN 5.693.043).

Applicants respectfully traverse the rejection because the cited prior art references do not teach or suggest each and every element of the claimed invention.

Heckele is the primary reference, with Kittrell being cited merely to teach a radiopaque catheter. Heckele pertains to a medical instrument having a hollow shaft made from tubular segments, some of which are connected by hinge mechanisms and can accordingly bend to curve the shaft. Control wires (10, 11) are placed through the wall of the shaft to allow an operator to adjust the curvature of the shaft by adjusting a knob in the handle of the device, which pulls the control wire(s) on one side of the shaft to curve the shaft in that direction. Significantly for the purposes of this discussion, the control wires are completely concealed within the device, as shown in Figure 1 of Heckele:



Claim 1 of the application recites "a plurality of tube wall bending indicators located at least on or within the catheter wall at a reference portion of the catheter to become curved where the catheter passes through an anatomical reference when the distal end of the catheter is at a target site within the patient's body; wherein the plurality of tube wall bending indicators provide an indication of tube wall bending to indicate the orientation of the reference portion of the catheter relative to the anatomical reference." One embodiment of these indicators can be best understood with reference to Figures 7A and 7B of the application, which are views of the proximal end of a shaft.



The indicators are rods or wires running through the wall of the shaft. As the shaft is bent, as in Figure 7B, the wires on the concave side of the bend extend out further and the wires on the convex side are pulled in. Thus the magnitude and orientation of a bend is indicated by the indicators.

It is asserted in the final office action that Heckele discloses these indicators in control wires 10 and 11, with Figures 2, 4 and 7 of Heckele cited in support of this argument. However, these are partial views as is clear from Figures 2, 4 and 7 and from the description of the figures. For example, Figure 2 is described as "an enlarged partial view of the shaft."

Col. 3, 1. 1. The control wires can be seen in these views because certain components of the device have been removed in the view to aid in the reader's understanding of the overall device.

As appellants explain above, in the device of Heckele, the control wires are not visible. This is illustrated in Figure 1, the only full view Heckele provides. Because the control wires are not visible, they cannot be indicators as claimed. The assertion in the Office Action that "Heckele discloses...a plurality of tube wall bending indicators at 10,11 locates [sic] at the eatheter wall which is capable of becoming curved when the eatheter is at a target site within the patient's body, where the plurality of tube wall bending indicators is able to provide an indication of the tube wall bending relative to the anatomical reference" is contracted by the teaching in Heckele that the control wires 10,11 are concealed by other components of the device.

Appl. No. 10/680,288
Pre-Appeal Conference Brief dated APRIL 20, 2009
Reply to Final Office Action dated November 20, 2008

As such, appellants respectfully maintain that the invention of claim 1 is non-obvious over Heckele in view of Kittrell when all words in the claim are properly considered.

Claims 3-4 and 22-23 were rejected as being unpatentable under 35 U.S.C. §103(a) over Heckele in view of Kittrell and Bullister (USPN 6,171,253). Applicants respectfully traverse the rejection because the modification of Heckele in view of Kittrell and Bullister has no reasonable chance of success.

Heckele in view of Kittrell is cited for the reasons given above with respect to claim 1. Bullister is cited as "teaching a tube wall having a plurality of strain gauges." However, the strain gauge of Bullister is a pressure sensor mounted on a thin diaphragm of the tube. Such a strain gauge is cannot be used to provide an indication of tube wall bending in the tube of Heckele. The strain gauge of Bullister is mounted on a single surface and is used to measure changes of the surface that correspond to changes in pressure in the main fluid channel. The tube of Heckele is composed of discrete segments that move in relation to each other to make the tube as a whole bend, but which as individual segments are rigid. A strain gauge of Bullister mounted on a segment, therefore, will not become curved with the tube and will not provide an "indication of tube wall bending" as claimed nor will such as strain gauge "determine the dimensional different (sic) between the tube wall" as asserted on page 3 of the Final Office Action. A strain gauge of Bullister mounted in such a fashion. Because the proposed modification will not function as asserted, there is no prima face case of obviousness over the cited references.

Claims 1-5, 22-31 and 33-34 were also rejected under 35 USC 112. It is not clear from the Advisory Action whether this rejection has been withdrawn because the Advisory Action is silent with respect to it. If this rejection has not been withdrawn, appellants respectfully traverse this rejection for the reasons discussed in the reply of January 20, 2009.

Appl. No. 10/680,288 Pre-Appeal Conference Brief dated APRIL 20, 2009 Reply to Final Office Action dated November 20, 2008

Reexamination and reconsideration are respectfully requested. It is respectfully submitted that all pending claims are now in condition for allowance. Issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

TOBY FREYMAN et al.

By their Attorney,

Date: \_\_ U~ La ~ Zou 9

J. Scot Wickhem, Reg. No. 41,376 CROMPTON, SEAGER & TUFTE, LLC

1221 Nicollet Avenue, Suite 800 Minneapolis, Minnesota 55403-2420 Telephone: (612) 677-9050

Facsimile: (612) 359-9349